

THE NEUROSURGICAL CENTER OF SOUTHWEST VIRGINIA
DOCTORS OF NEUROLOGICAL SURGERY

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GENERAL NEUROSURGERY
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SPINAL SURGERY

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Document Management Branch (HFA-305 Food and Drug Administration)
5630 Fisher's Lane
Room 1061
Rockville, MD 20852

RE: Proposed Regulations of Converting the Classification
Of Human Tissues to Medical Devices

To Whom It May Concern:

This is a followup letter to one that I generated on December 7th, 1999, when I rendered my opinion about the regulation of bone grafts used as allografts from bone banks. I wish to reiterate this position. I cannot believe that this situation is still being considered after you have reviewed the position paper* on the use of bone dowels for human tissues. I continue to use tricortical iliac allografts. I have not run into any problems with quality concerns; it has proven to be efficacious and safe, and it is in the patient's best interest as alternatives of using autograft requires a longer surgery, added morbidity to the graft site, does not enhance fusion at all, and requires prolonged hospitalizations and costs in terms of operative time and hospitalization. As I have failed to see any evidence for any untoward infectious side effects from grafts in all my experience so far, I cannot see why this consideration is even being entertained to put more onus and burdensome regulation on a situation that is not a problem. As they say, "If it ain't broken don't fit it," I think this applies critically to any consideration of reclassifying human tissues to medical devices.

* AANS

Yours truly,

Laurence I. Kleiner
Laurence I. Kleiner, M.D.

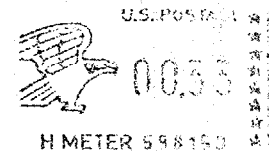
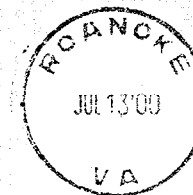
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